IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

DEY, L.P. and DEY, INC.,	:	
	:	
Plaintiff,	:	
	:	
v.	:	Civil Action No. 08-372-JJF
	:	
SEPRACOR, INC.,	:	
	:	
Defendant.	:	

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MEMORANDUM OPINION

January 30, 2009
Wilmington, Delaware

Joseph J. Farnan Jr.
Farnan, District Judge

Presently before the Court is Defendant Sepracor's Motion To Dismiss for lack of subject matter jurisdiction. (D.I. 8.) For the reasons discussed, the Motion will be denied.

I. PROCEDURAL BACKGROUND

On June 20, 2008 Plaintiffs Dey L.P. and Dey, Inc. (collectively, "Dey") brought this action, seeking a declaratory judgment that their proposed generic levalbuterol hydrochloride inhalation products, if marketed, would not infringe U.S. Patent No. 6,341,289 ("the '289 patent"), which is owned by Defendant Sepracor. (D.I. 1.) On August 13, 2008, Sepracor moved to dismiss for lack of subject matter jurisdiction, alleging that there is no justiciable controversy regarding infringement or validity of the '289 patent. (D.I. 8; D.I. 9.)

II. FACTUAL BACKGROUND

A. The Hatch-Waxman Statutory Scheme

Requisite to an understanding of the instant dispute is a basic understanding of the Hatch-Waxman statutory scheme, which governs the approval of new and generic dugs. See 21 U.S.C. § 355; 35 U.S.C. §§ 156, 271(e). The Hatch-Waxman statutory scheme is most easily understood if one keeps in mind that it was devised with the aim of striking a "balance between two competing policy interests: (1) inducing pioneering research and development of new drugs and (2) enabling competitors to bring

low-cost, generic copies of those drugs to market." Andrx Pharms., Inc. v. Biovail Corp., 276 F.3d 1368, 1371 (Fed. Cir. 2002).

Under Hatch-Waxman, a pioneer drug manufacturer that has had its drug approved by the FDA must notify the FDA of all patents it owns "with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." 21 U.S.C. § 355(b)(1). These patents are listed in an FDA publication commonly referred to as the "Orange Book." Those seeking to manufacture a generic version of a pioneer drug may submit to the FDA an abbreviated new drug application ("ANDA"), which, rather than relying on independent safety and efficacy studies, may simply rely on those previously done by the pioneer. The generic manufacturer need only submit information showing the generic's bioequivalence to the pioneer product. See 21 U.S.C. § 355(j)(2)(A). With the ANDA, the generic manufacturer must further include one of four certifications regarding each of the patents listed in the Orange Book for the pioneer drug. See 21 U.S.C. § 355(j)(2)(A)(vii)(I-IV). At issue in this case is the so-called "Paragraph IV" certification, which is a statement that the Orange Book patent for the pioneer drug is invalid and/or not infringed by the proposed generic.

After receiving notice of any Paragraph IV certifications, the patent holder has 45 days to sue the ANDA applicant for infringement. If the patent holder does not bring suit within this period, the FDA may approve the ANDA. See 21 U.S.C § 355(j)(5)(B)(iii). However, if the patent holder sues, the FDA may not approve the ANDA until entry of a final judgement that each relevant Orange Book patent is not infringed or is invalid, the patents expire, or thirty months have passed, whichever is earlier. Id.

To incentivize drug manufacturers to file ANDAs with Paragraph IV certifications and, though subjecting themselves to suit, challenge questionable Orange Book patents, the Hatch-Waxman scheme provides that the first generic manufacturer to file an ANDA with a Paragraph IV certification will be granted 180 days of market exclusivity. During this 180-day exclusivity period, the FDA may not approve later filed ANDAs based on the pioneer's NDA. See 21 U.S.C § 355(j)(5)(B)(iv).

Under the pre-2003 version of Hatch-Waxman, the 180-day exclusivity period could be "triggered" by either the first Paragraph IV ANDA filer's commercial marketing of its generic drug product, or a court decision of non-infringement or invalidity of the Orange Book patents. Importantly, only the first Paragraph IV ANDA filer could begin the 180-day exclusivity period via the commercial-marketing trigger. In these

circumstances, if the pioneer could convince the first-filer to delay going to market, perhaps via a favorable settlement agreement, then subsequent ANDA filers would be blocked from going to market while they waited for the first filer to complete its exclusivity period. This situation is commonly referred to as "parking" of the exclusivity period. See, e.g., Apotex, Inc. v. Pfizer Inc., 385 F. Supp. 2d 187, 189-90 (S.D.N.Y. 2004). The only recourse of subsequent ANDA filers was to trigger the first filer's exclusivity period via a successful court judgment. However, if the pioneer successfully refuses to litigate with the subsequent ANDA filer and instead, for instance, offers a covenant not to sue, the subsequent ANDA filer would remain locked out of the market until after the primary filer completes its exclusivity period.

Recognizing that such a situation obstructs the policy objectives of the Hatch-Waxman act, in December 2003 Congress passed Title XI of the Medicare Modernization Act of 2003 ("MMA"). The MMA replaced the exclusivity period triggering provisions with new "forfeiture" provisions. These provisions are designed to, among other things, curb "parking" of the exclusivity period. Under the current version of the statute, the 180-day exclusivity period is triggered only when the first ANDA filer takes its generic to market. However, the MMA sets forth a number of "forfeiture events" that result in the total

elimination of the exclusivity period. See 21 U.S.C. § 355(j)(5)(D)(i). For example, a primary ANDA filer that, for some reason, is not sued by the NDA holder, will lose its exclusivity period if it fails to go to market within 75 days after its ANDA is approved. 21 U.S.C. § 355(j)(5)(D)(i)(I)(aa)(AA). Likewise, a primary ANDA filer will lose its exclusivity period if it fails to take its generic to market within 75 days after a court judgment of invalidity or non-infringement. 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(AA).

Thus, under both the pre-2003 and current versions of Hatch-Waxman, a subsequent ANDA filer can hasten its entry into the market by establishing the invalidity or non-infringement of the NDA holder's Orange Book patents.[1] Caraco Pharm. Labs., Ltd. v. Forest Labs., Ltd., 527 F.3d 1278, 1286 (Fed. Cir. 2008) ("[U]nder both the original and amended 180-day provisions, the ability of subsequent Paragraph IV ANDA filers to obtain FDA approval depends on the date of a final court decision holding the relevant Orange-Book-listed patents invalid or not

[1] Under the pre-2003 Hatch-Waxman Act, a secondary ANDA filer that triggers the onset of the exclusivity period by a court judgment would need to wait a maximum of 180 days before going to market. However, under the current version of Hatch-Waxman, the waiting period could be extended to 254 days. This is because forfeiture of the 180-day exclusivity period would not take place until 75 days after the court judgment. Thus, after a court judgment, a primary ANDA filer could wait 74 days before going to market and then enjoy its exclusivity period for an additional 180 days, forcing the secondary filer wait 254 days total.

infringed."). To further facilitate the ability of subsequent ANDA filers to obtain a court judgment of non-infringement or invalidity of the NDA holder's Orange Book patents, Congress extended the relevant federal court declaratory judgment jurisdiction under 28 U.S.C. § 2201 "to the extent consistent with the Constitution." 35 U.S.C. § 271(e)(5); see also Teva Pharm. USA, Inc. v. Novartis Pharm. Corp., 482 F.3d 1330, 1335 (Fed. Cir. 2007) ("Title 35 U.S.C. § 271(e)(5) is a 2003 amendment to the patent statute that works in conjunction with the 2003 amendment to the ANDA statute" to provide declaratory judgment jurisdiction "to the extent consistent with the Constitution. . . ."). The Court must now decide whether it may, consistent with the Constitution, assume jurisdiction over a declaratory judgment action with facts, set forth below, that may implicate concerns addressed by the amended Hatch-Waxman Act.

B. The Relevant Litigation History

Defendant Sepracor is the holder of an approved NDA for various forms of levalbuterol hydrochloride inhalation solutions that are used in the treatment of bronchial disorders and that go by the trade name Xopenex®. Sepracor listed six patents in the Orange Book for Xopenex®: U.S. Patent Nos. 5,362,755; 5,547,994; 5,760,090; 5,844,002; 6,083,993; and 6,451,289 (the "'289 patent"). At some point near June 2005, a generic drug company, Breath, filed an ANDA – with a Paragraph IV certification for all

six patents - that sought approval to market generic versions of Xopenex®. (D.I. 9 at 4-5.) As the first Paragraph IV ANDA filer, Breath is entitled to the 180-day exclusivity period for generic Xopenex®. In October 2005, Sepracor sued Breath on all six Orange Book patents in the Northern District of Illinois. (Id.) In early 2008, the lawsuit settled, with the parties agreeing that Breath would be allowed to enter the market pursuant to a royalty-bearing license in August 2012, which is prior to the expiration of three of the six Xopenex® patents. (Id. at 5-6.)

In July 2005 Plaintiff Dey filed its own Xopenex® ANDA with Paragraph IV certifications for all six Orange Book patents. (Id. at 4.) Dey notified Sepracor of its ANDA in January 2006, and in February 2006, Sepracor sued Dey in this Court on five of the six Xopenex® patents, electing not to assert the '289 patent. (Id. at 4.) Dey later filed another ANDA seeking to market a "concentrate" version of Xopenex®, which it notified Dey of in August 2006. Sepracor again sued on only the five patents that it asserted in response to Dey's first ANDA.[2] (Id. at 6.) On June 20, 2008 Dey brought this action, seeking a declaratory judgment that their proposed ANDA products, if marketed, would not infringe the '289 patent. In response, on August 12, 2008,

[2] These two lawsuits were consolidated in this Court as Civil Action No. 06-113. (D.I. 262 in 06-113.)

Sepracor provided Dey with a covenant not to sue on the '289 patent. (D.I. 9 at 6.) Based on this covenant, Sepracor contends that Dey is not under threat of suit on the '289 patent and that this case should be dismissed for lack of subject matter jurisdiction.

Dey, however, contends that by suing on only five of the six Xopenex® patents, Sepracor has "created a legal barrier that Delays Dey's product from entering the market." (D.I. 11 at 10.) Specifically, Dey notes that even if they are ultimately successful in invalidating the five Xopenex® patents that Speracor did assert, it will still be unable to immediately enter the market because the FDA will be prohibited from approving Dey's ANDA until Breath, the first Paragraph IV ANDA filer, has enjoyed its 180-day exclusivity period. (Id. at 8-9, 12-13.) Because of the settlement agreement between Sepracor and Breath, Dey notes that this cannot happen until August 2012, and then only if Breath chooses to promptly take its generic to market. Should Breath choose otherwise, the entry of Dey's generic into the market could be delayed until as late as 2021, when the '289 patent expires. (Id. at 12.)

This potential for delay, Dey contends, is a cognizable injury-in-fact that can be redressed through the instant declaratory judgment action. Sepracor, by contrast, contends that delay remains contingent upon Dey achieving litigation

success on two particular asserted Xopenex® patents that do not expire until after 2012. This is so, Sepracor argues, because if Dey is unable to invalidate these two patents or show that the generic would not infringe them, Breath's 180-day exclusivity period, which Sepracor contends will begin in 2012, will expire long before Dey can take its generic to market. (D.I. 9 at 12.) As to Dey's concern that Breath may delay taking its generic to market until after 2012, Sepracor contends that this is conjectural at best and nonsensical at worst. According to Sepracor, "Breath makes money by selling products" and would not reasonably delay doing so. (D.I. 14 at 9.)

III. DISCUSSION

The Declaratory Judgment Act "requires an actual controversy between the parties before a federal court may exercise jurisdiction." 28 U.S.C. § 2201(a) (2000); EMC Corp. v. Norand Corp., 89 F.3d 807, 810 (Fed. Cir. 2004) (overruled in part on other grounds, MedImmune, Inc. v. Genentech, Inc., 549 U.S. 118 (2007)). Plaintiffs bear the burden of proving the existence of an actual controversy by a preponderance of the evidence with regard to their declaratory judgment complaint. Shell Oil Co. v. Amoco Corp., 970 F.2d 885, 887 (Fed. Cir. 1992).

Following the Supreme Court's decision in MedImmune, Inc. v. Genentech, Inc., 549 U.S. 118 (2007), the Federal Circuit has acknowledged that the "reasonable apprehension of suit test is no

longer a necessary criterion for declaratory judgment jurisdiction." Instead, jurisdiction over a declaratory judgment requires that "the dispute be definite and concrete, touching the legal relations of parties having adverse legal interests and that it be real and substantial and admit of specific relief through a decree of conclusive character, as distinguished from an opinion advising what the law would be upon a hypothetical state of facts." MedImmune, 549 U.S at 127 (citations omitted). Providing guidance as to whether this standard is met in the Hatch-Waxman context are the recent Federal Circuit decisions Caraco Pharm. Labs., Ltd. v. Forest Labs., Ltd., 527 F.3d 1278 (Fed. Cir. 2008) and Janssen Pharmaceutica, N.V. v. Apotex, Inc., 540 F.3d 1353 (Fed. Cir. 2008).

In Caraco, as in this case, the patent holder, Forest Laboratories, Inc. ("Forest"), listed multiple patents in the Orange Book in relation to its NDA. Caraco, 527 F.3d at 1286. Specifically, there were two Orange Book patents: the '712 patent, which expires in 2012, and the '941 patent, which expires in 2023. Also, like the instant case, there were two Paragraph IV ANDA filers: Ivax Pharmaceuticals, Inc. ("Ivax") filed the first ANDA, and Caraco Pharmaceutical Laboratories, Ltd. ("Caraco") filed the second ANDA. Id. at 1286, 1288. Both Ivax's ANDA and Caraco's ANDA pertained to the two listed patents. Id. at 1286, 1288. However, after Ivax filed its ANDA,

Forest chose to sue only on the '712 patent, which was ultimately found valid, infringed, and enforceable. Id. at 1286. Later, after Caraco filed its ANDA, Forest sued Caraco on only the '712 patent, granting Caraco a covenant-not-to-sue on the '941 patent. In these circumstances, even if Caraco were to have achieved victory on the '712 patent, it would have been unable to go to market until Ivax completed its 180-day exclusivity period on the '941 patent, which could be no earlier than 181 days after the expiration of the '712 patent. Hoping to trigger Ivax's 180-day exclusivity on the '941 patent, and hence put itself in a position to enter the market earlier, Caraco brought a declaratory judgment action for non-infringement of the '941 patent. In holding that the district court had jurisdiction over the declaratory judgment action, the Federal Circuit explained that "[i]n claiming that it has been denied the right to sell non-infringing generic drugs, Caraco has alleged precisely the type of injury that the Declaratory Judgment Act is designed to remedy." Id. at 1294.

Shortly after Caraco, the Federal Circuit issued its decision in Janssen, which has facts very similar to Caraco, but with an important twist, which is detailed below. In Janssen, there were three Orange Book patents: the '663, '425, and '587 patents. Janssen, 540 F.3d at 1358. The first ANDA filer was Teva Pharmaceuticals USA, Inc. ("Teva"). However, Teva's ANDA

did not include Paragraph IV certifications for all of the Orange Book patents. Rather, Teva's ANDA included Paragraph IV certifications for the '425 and '587 patents and a Paragraph III certification for the '633 patent. Respecting, the validity of the '663 patent, Teva's Paragraph III certification merely informed the FDA of the '663 patent's effective expiration date (June 2008). Under Hatch-Waxman, the FDA would then delay approval of Teva's ANDA until that date. Id. at 1358; 21 U.S.C. § 355(j)(2)(A)(vii)(III). The patent holder in Janssen elected not to assert the '425 and '587 patents against Teva. Nevertheless, as the first Paragraph IV filer on the '425 and '587 patents, Teva was still entitled to 180-days of exclusivity upon going to market, which, by virtue of its Paragraph III certification for the '663 patent, could be no earlier than the expiration of the '663 patent in June 2008. The second ANDA filer in Janssen was Apotex, Inc. ("Apotex"), which, unlike Teva, ultimately filed Paragraph IV certifications for all three Orange Book Patents. Janssen, 540 F.3d at 1358.

Rather than decline to sue, as it did with Teva, the patent holder chose to assert the '663 patent against Apotex, withholding the '425 and '587 patents from litigation. Apotex then counterclaimed for declaratory judgment of non-infringement of the '425 and '587 patents, claiming that without a judgment of non-infringement of these patents, it would be blocked from going

to market until after Teva completed its 180-day exclusivity period on these patents. In response, the patent holder presented Apotex with a covenant not to sue on the '425 or '587 patents and requested that Apotex drop its declaratory judgment counterclaims. Maintaining that the covenant did not address the core problem of Apotex's market entry being delayed, Apotex refused to drop its counterclaims. Id. at 1359.

If the exposition of facts in Janssen is halted at this stage, then Janssen is no different from Caraco in any meaningful respect. Importantly, the harm at issue in both cases would be the same. Specifically, because the pioneer drug patent holder elected not to sue a second Paragraph IV ANDA filer on all Orange Book patents, the second ANDA filer, without a declaratory judgment action, would, because of the delayed onset of a primary ANDA filer's exclusivity period, face a definite inability to bring its generic to market until at least 181 days after the expiration of one asserted patent. In Caraco, because Ivax was unsuccessful in litigating the '712 patent, Caraco would have been forced to wait at least 181 days after expiration of the '712 patent to bring its product to market, the earliest point by which Ivax could have completed its 180-day exclusivity period. Likewise, in Janssen, because Teva filed only a Paragraph III certification on the '663 patent, Apotex would have been forced to wait until at least 181 days after expiration of the '663

patent to bring its product to market, the earliest point by which Teva could have enjoyed its 180-day exclusivity period. Furthermore, in both cases, if the primary ANDA filer for some reason elected not bring its generic to market as soon as permitted, the second ANDA filer would be forced to wait even longer.

In Janssen, however, an important difference presented itself that made the case distinguishable from Caraco and caused the Federal Circuit to conclude that declaratory judgment jurisdiction could not be exercised. Specifically, for reasons that are unclear, Apotex stipulated to the validity, infringement, and enforceability of the '663 patent after filing its declaratory judgment counterclaims on the '425 and '587 patents. Janssen, 540 F.3d at 1360. In these circumstances, the potential harm to Apotex changed. Now, Apotex - by virtue of its own stipulation - eliminated any possibility of going to market prior to the expiration of the '663 patent, even if it emerged victorious on its proposed declaratory judgment counterclaims. Rather, by achieving victory on its proposed counterclaims, the only definite harm that Apotex could have eliminated was the need to wait - upon expiration of the '663 patent - 180 days for Teva to complete its exclusivity period before going to market. Indeed, the elimination of this harm would result from Apotex triggering Teva's 180-day exclusivity period at a time when Teva,

by virtue of its Paragraph III certification, would actually be unable to go to market. Id. at 1360. Noting the "clear" "import" of the incentive provided by the 180-day exclusivity period, the Federal Circuit held that Apotex's exclusion from the market during Teva's exclusivity period did not present a justiciable Article III controversy. Id. at 1362. Furthermore, to the extent Apotex complained that Teva might delay enjoying its 180-day exclusivity period until some undetermined time after expiration of the '663 patent, the Federal Circuit held that such harm was too speculative to create a justiciable controversy. Id. at 1363.

In the Court's view, the instant case is intermediate to Caraco and Janssen. Like Janssen, there appears to be a possibility that if the Court were to recognize declaratory judgment jurisdiction, the primary ANDA filer, Breath, could lose its 180-day exclusivity period. Specifically, because of the settlement agreement between Breath and Sepracor, Breath may not go to market until August 2012.[3] If, more than 254 days prior to this,[4] Dey were to attain a court judgment of non-infringement or

[3] The parties dispute whether this is the case. (See D.I. 16 at 3; D.I. 17 at 3.) For the purposes of this Motion, the Court will assume that under the settlement agreement Breath is absolutely prohibited from going to market until August 2012 at the earliest.

[4] While Caraco and Janssen were decided under the pre-2003 version of Hatch-Waxman, the current case must be decided under the current version of Hatch-Waxman. Accordingly, Breath would have 75 days to begin marketing before forfeiting its 180-day

invalidity of Sepracor's Orange Book patents, Breath's exclusivity period would be completed entirely before Breath could go to market.

However, unlike Apotex in the Janssen case, Dey has not precluded itself from going to market prior to the primary ANDA filer. Indeed, Dey has not, like Breath, agreed to forego marketing its generic until August 2012. Put another way, in the instant case, the Court finds nothing equivalent to Apotex's stipulation to the infringement and validity of the '663 patent. In Janssen, it was this stipulation that was determinative, not, as Sepracor contends, the possibility of Teva losing its 180-day exclusivity period. Janssen, 540 F.3d at 1360 ("We agree with the parties that if Apotex had not stipulated to the validity of the '663 patent, then Caraco would have been controlling."). To the extent the Federal Circuit noted the possibility of Teva losing its 180-day exclusivity period, it was only against the backdrop of Apotex's stipulation. As a result of the stipulation, Apotex placed itself on equal footing with Teva with respect to the earliest date it could conceivably enter the market. In these circumstances, the Federal Circuit noted that the only remaining non-speculative harm to Apotex was the possibility of having to wait 180 days for Teva to enjoy its exclusivity period following expiration of the '663 patent, a

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exclusivity period.

"result envisioned by the Hatch-Waxman act" to create "an incentive to challenge suspect Orange Book listed patents." Jannsen, 540 F.3d at 1362. Here, by contrast, Dey has not stipulated to be on equal footing with Breath. Thus, unlike as in Janssen, if Dey were to prevail on its declaratory judgment action, the sole effect would not be to simply destroy Breath's exclusivity period. Rather, Dey could also potentially go to market well in advance of August 2012, the earliest date that Breath could go to market under its settlement agreement with Sepracor. On these facts, the Court finds that the policy objectives of the Hatch-Waxman Act, particularly the 2003 amendments thereto under the MMA, tilt towards granting declaratory judgment jurisdiction. As the Federal Circuit explained in Caraco, Hatch-Waxman aims to "balance the need for pharmaceutical innovation with the need for generic drug competition," and a significant aspect of this is to encourage the "early resolution of patent disputes when subsequent Paragraph IV ANDA filers are blocked by a first generic applicant's 180-day exclusivity." Caraco, 527 F.3d at 1294.

Accordingly, in the Court's view, the instant case is more like Caraco than Janssen. Following Caraco, the Court concludes that Dey's declaratory judgment action presents a justiciable Article III controversy. See Caraco, 527 F.3d at 1291-97; see also D.I. 11 at 10-18.

IV. CONCLUSION

For the reasons discussed the Court will deny Sepracor's Motion To Dismiss.

An appropriate Order will be entered.